

USER MANUAL FOR

RIDA[®]

X-Screen



- Urgently to be read before initial operation
 - Observe safety instructions

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1 GENERAL

Purpose

The **RIDA® X-Screen** is an instrument that evaluates the reflection or optical density of a biochemical reaction compared to the environmental background of the measured sample.

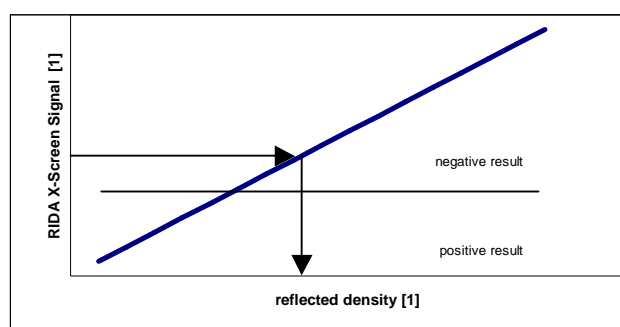
Performance features

The **RIDA® X-Screen** can detect optical density signals of 0.25 % or greater. When there is an optical density of 5 %, reproducibility of 0.2 % optical density can be achieved.

The performance of the **RIDA® X-Screen** is heavily dependent on the computer used, however it is possible to read a test every 30 seconds. In order to achieve this optimum performance level it is recommended to use the computer specified.

Output of analytical data

Measurement values of the **RIDA® X-Screen** are correlated linearly to the reflected density measurements of the control function. Optical densities are divided into several segments. The figure shows a high signal generated by the **RIDA® X-Screen**. The measurement of the reflected density allows the interpretation of a negative test result.



Scope of use

During the set up routine, different tests, released by the manufacturer, are transferred on the personal computer. These tests cover the product and scope of use of the Reader provided by the manufacturer.

Application not recommended by the manufacturer

This instrument only should be used for measurement and evaluation of tests, released by the manufacturer. The manufacturer excludes warranty when other tests are used.

Safety instructions and cautions

Correct capture and treatment of the tests only is possible when the test used has been handled according to its instruction sheet.

Especially one should care for time limits and sample quantity, as these factors have a great influence on the measurement results.

Action in case of emergency

In case of samples taken of patient cases of emergency these samples can be examined at every time by interrupting the routine work and performing the examination according to the instruction sheet.

2 EQUIPMENT SUPPLIED • REMARKS

Packing list

- 1 RIDA® X-Screen-Reader instrument
- 1 Test membrane holder
- 1 CD-ROM with RIDA® X-Screen Reader software
- 1 control sample
- User Manual
- Brief instructions

Order Number

- ZG1101

Advice: Should any piece of equipment be missing or damaged, please contact your distributor.

IMPORTANT !

- Please read this manual entirely prior to first use.
- Follow the instruction closely.
- R-Biopharm AG is not responsible for any damage occurring due to misuse or wrong handling of soft- and hardware.
- See the license agreements for further details (page 32).
- **Do not connect the RIDA® X-Screen reader device to the PC before having installed the software completely.**

If you have any questions concerning handling of soft- or hardware, please contact R-Biopharm AG or your distributor by phone, fax or email:

Telephone + 49 (0) 61 51 81 02 – 0

Telefax + 49 (0) 61 51 81 02 – 40

e-mail info@r-biopharm.de

Order orders@r-biopharm.de

Address R-Biopharm AG
An der neuen Bergstraße 17
64297 Darmstadt
Germany

This manual has been edited conscientiously and complies with the Norm DIN EN 591.

3 TECHNICAL SPECIFICATIONS

STORAGE • SETTINGS

This system can be applied according to the conditions of EN 61326 : 1997 + A 1:1998 (Class: B) for emission and absorption.

Dimensions: 262 x 110 x 200 mm³ (H x W x L)

Weight: 0.9 kg

Physical data: 5 V  / 0.5 Ampere

Consumption: maximally 2.5 Watt

Storage and operating temperature: Storage temperature should not be under 0 degree and not over 50 degrees Celsius.

Location or rather operating temperature of the instrument should not be under 10 degrees and not over 40 degrees Celsius.

Basic settings: The factory-made basic settings are conducted by the set up routine and can be verified in the manual, chapter: control sample - quality control.

Measures of installation: The instrument should not be exposed to direct and permanent radiation of sun or light. Please pay attention for the operating and storage temperature.

Please follow the installation instructions.



On the rear side of the the **RIDA® X-Screen** a “Warranty”-Seal is adhered.

This seal serves to prohibit unauthorized unscrewing or dismantling of the the **RIDA® X-Screen** device.

Breaking of the “Warranty”-Seal is considered to be a breach of warranty.

Warranty claims will not be accepted if the “Warranty”-Seal is broken.

4 SYSTEM REQUIREMENTS

System requirements

- Operating system: Windows XP, Windows Vista, Windows 7 (all 32 Bit versions)
See Operating System requirements
- Win NT / Win 98/98 SE, Win ME, Win 2000 are **not** supported
- Hard disk space: 10 GB
- CD-ROM: 24x speed or better
- Display resolution: min 1024x768 / 16 bit colour or better
- 1 free USB port

4 SYSTEM REQUIREMENTS

SOFTWARE INSTALLATION

Installation

- First keep the RIDA[®] X-Screen **disconnected**.
- Put the enclosed RIDA[®] X-Screen program CD in your CD drive.
- If your system supports Autorun, the setup program will launch itself.
- If not:
 - go to **START/RUN**
 - type in **X:\install** (X = letter of your CD path)
 - then press **ENTER**

After installation of the software, please connect the RIDA[®] X-Screen device with a free USB port of your PC.

To interrupt power supply, remove the USB plug of the RIDA[®] X-Screen from the PC USB port.

4 SYSTEM REQUIREMENTS

SYSTEM CHECK

System check

The installation program tests all essential points of the installed components in the computer. The **RIDA® X-Screen** has special system requirements.

| Test function | Minimum requirements | Error handling |
|---|--|--|
| Operating System | Windows XP Windows Vista Windows 7 | Windows 3.1 / 95 / 98 / 98SE / ME, 2000 are detected: The computer is not adapted for the installation of the software. Error correction: Installation of an appropriate operating system (any existing data should be stored on external media) |
| Processors: | Minimum 1 | |
| RAM | Windows XP Windows Vista Windows 7 | See "Operating System" requirements |
| Graphic resolution Graphic depth | Minimum 1024 x 768 Pixel 16 bit or more | Resolution 1024x768 Pixel not found. The graphic card is not sufficient for this program. The resolution is not adequate. Error correction: Change the current graphic card and use a card with a resolution of minimum 1024 x 768 with a color depth of 16 bits or more |
| Current Colors | The current settings do not correspond to the required values but will be supported by the graphic card. | Refer to the manual "Monitor Resolution" |
| Hard drive (free) | Minimum 10 GB | The hard disk space (free) is less than 850 MB. Delete files that are not required from the hard drive or increase the size of the hard drive. (Data should be stored on external media). |
| Printer (default) | Printer installed. A printer is installed and connected to a port. This printer will be used as an output unit for the software. | No printer installed. It is strongly recommended to install a printer for the printout of the results. |
| Printer (installed) | List of the installed printers. | |

5 USER ADMINISTRATION

PROGRAM START • USER LOGIN

User administration

The **RIDA® X-Screen** offers a comfortable user administration.

Therewith every user can choose and equip program functions and program options individually and flexibly.

User login

After program start:

- type in user name.
- type in password.

Advice:

At the first program start the administrator login with the password “**admin**” (please type in admin in lower case letters.)

Recommendation: Choose a new password after the first program starts.

In the program (see picture next page)

EXTRA ► CHANGE ► ADVANCED ► USER ACCOUNT ► MODIFY USER ACCOUNT



proceed login by using

Continue

The program starts by using the correct password and the settings, which were defined by the user.

5 USER ADMINISTRATION

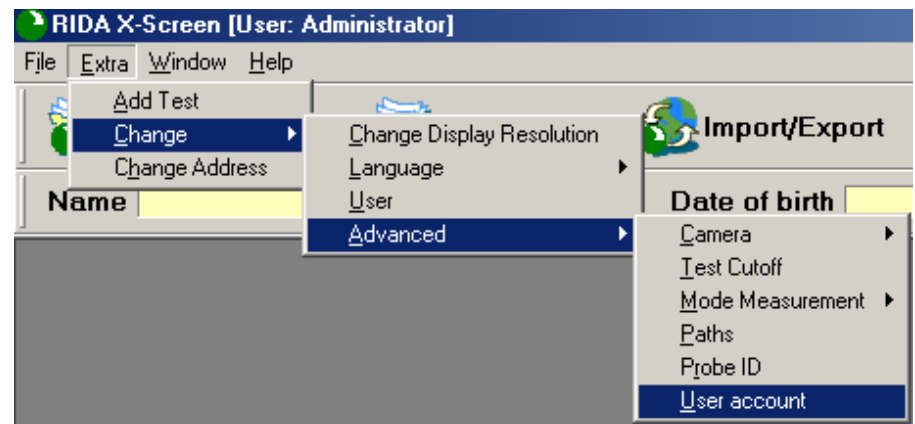
USER PROFILES

User profiles

With the program module **User account** you can **add**, **modify** or **delete** an user account quickly and easily.

In the program:

EXTRA ▶ CHANGE ▶ ADVANCED ▶ USER ACCOUNT



Survey

Already established user profiles will be shown with **name** and status **active** (YES/NO) see below

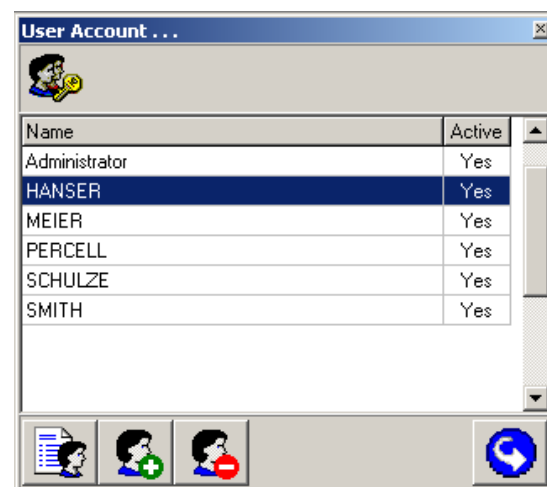
User status

- Active status: **YES**

The user is able to start the program.

- Active status: **NO**

The user is not able to start the program.



5 USER ADMINISTRATION

USER PROFILE • ICONS

Icons

The options of the user administration are accessible by using the following 4 icons.



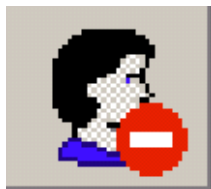
Modify User Account

Changing the functions of an user profile.



Add User Account

Adding a new user profile.



Delete User Account

Deleting an user profile.



Close User Account

Leaving the user administration.

if

Add User

or

Modify User

is activated, a

window for changing the user profile

appears.

5 USER ADMINISTRATION

USER PROFILE • OPTIONS

| OPTIONS | DESCRIPTIONS |
|-----------------------------------|--|
| User | Name of the user Allowed signs: A ... Z, a ... z, 0 ... 9 |
| Password | Type in password Allowed signs: A ... Z, a ... z, 0 ... 9 |
| Password confirm | Type in password Allowed signs: A ... Z, a ... z, 0 ... 9 |
| Active | ✓ = the user is able to start the program |
| Administrator | Only the program administrator can use all program functions inclusive the user administration. The user profile ADMINISTRATOR <u>can not</u> be deleted. |
| Add test | Adds a new test In the program: EXTRA ► ADD TEST |
| Change patient's data | Changes the patient's data or other data base information. |
| Comments | Adds comments to the single measurements. |
| Delete examination / patient | Deletes single measurements and/or patient's data. |
| Examination import / export | Can import or export single measurements. |
| Examination validation | Can validate single measurements. |
| Measurement | Can perform examination/measurement of patient samples. |
| Printout | Prints out the measurement results. |
| Sample ID modify | Changes the sample ID numbers. |
| Service module | Can change the internal program settings. |
| Open measurement / patient's data | Archived data can be opened and regarded from the data bank. |

6 MENU BAR

PROGRAM OPTIONS

| MAIN MENU | SUB MENU | DESCRIPTION |
|--|------------------------|---|
| File ▶ ▶ ▶ ▶ ▶ ▶ | New examination | Creates a new examination for an existing patient |
| | Load patient | Loads a patient and its existing examinations |
| | Import / Export | Allows data transfer between RIDA® X-Screen-Readers |
| | Setup Print | Allows to select the printer |
| | Print | Allows preview of a printout |
| | Exit | Closes the program |

| | | |
|--|-----------------------|---|
| Extra ▶ ▶ ▶ | Add test | Adds a new test |
| | Change | ▶ LANGUAGE ▶ Select desired languages ▶ ADVANCED ▶ Mode Measurement ▶ Practise/Laboratory ▶ Path = Service Module ▶ Sample ID ▶ on/off ▶ User Account ▶ see chapter 5 ▶ USER |
| | Change address | Edits the data of the performing laboratory |

| | | |
|--|--------------------------|---------------------------|
| Window ▶ ▶ ▶ ▶ | Cascade | Cascades all open windows |
| | Tile | Tiles all open windows |
| | Close all windows | Closes all open windows |
| | Show exam. list | Shows all open windows |

| | | |
|------------------------|--------------------------|---|
| Help ▶ ▶ | Technical support | Shows the address of the technical support concerning help about the RIDA® X-Screen software |
| | About | Shows copyright information |

7 ADDING A NEW TEST

System-Key

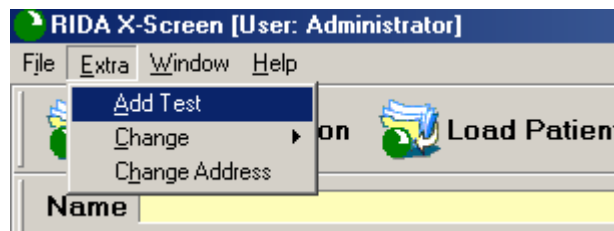
Each test membrane holder and **RIDA® X-Screen** has got its own system-key. This key already has been entered while installing.

New Test

In the program:

MENU BAR

EXTRA ► ADDTEST

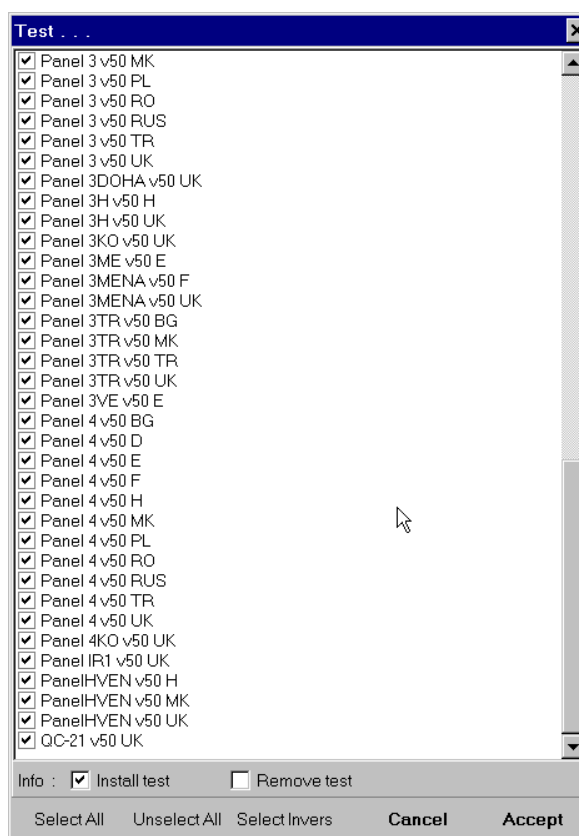


The camera will detect the correct **RIDA® X-Screen** device automatically:

A window will open automatically:

All tests released from the manufacturer are depicted in the Test Explorer window.

- By clicking on **Select all**, you can select all tests.
- By clicking on **Unselect all** you can call off all selected tests.
- By clicking on **Select invers** you can convert all selected tests into not selected tests or convert all not selected tests into selected ones.
- Continue with **Accept**



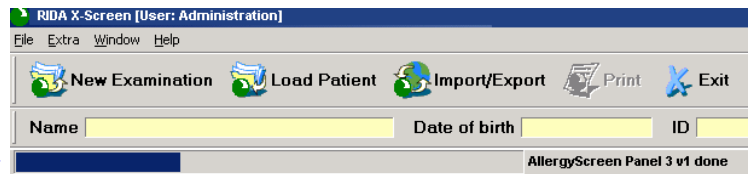
Caution:

If this window pops up asking for a system key number it is a sign that the **RIDA® X-Screen** has not been connected properly to the computer used. Measures:

- Exit the software
- Shut down computer
- Connect RIDA® X-Screen to the PC
- Start software again



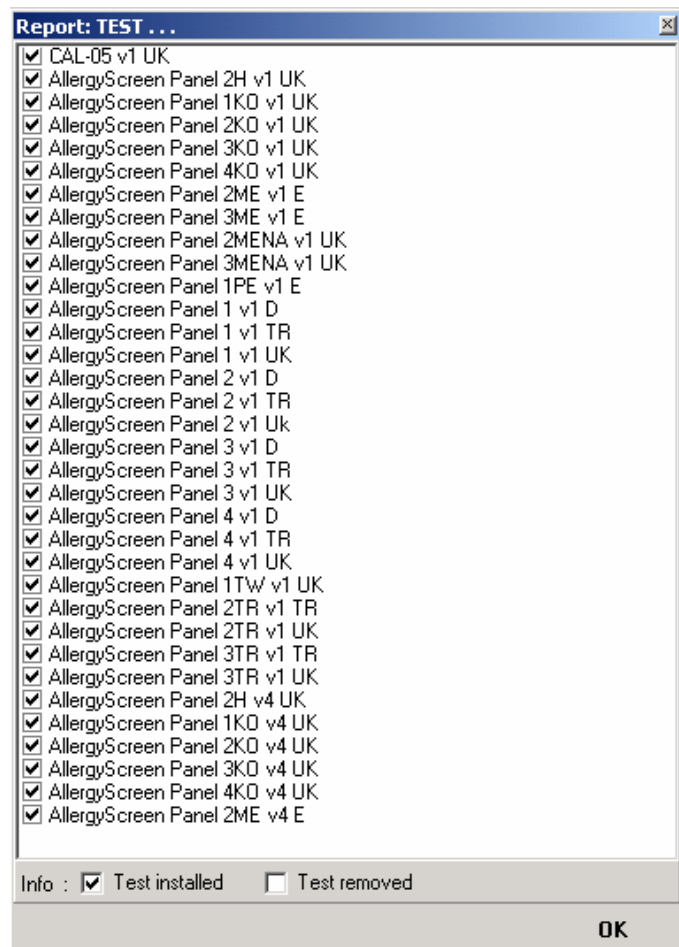
- The blue running bar and the test text inform about the installation process of the tests



- The installation may take a few seconds

- After completion of the installation a test report is depicted for all installed tests.

- Continue with **OK**



8 ADDING A NEW PATIENT

OPENING • CHANGING PATIENT'S DATA

Adding a patient

In the program:

MENU BAR



NEW EXAMINATION

- click on **Add** to confirm

Explorer - Set New Examination

Name: Firstname: Date of birth: ??-??-????

ALL | AB | CD | EF | GH | IJ | KL | MN | OP | QR | ST | UVW | XYZ

| Lastname | Firstname | Group | Date of birth |
|------------|-----------|-------|---------------|
| ABEL | BERND | ALL | 15.10.58 |
| ALFRED | BEN | METH | 11.12.71 |
| ANTON | RAINER | BAR | 15.07.64 |
| ATLAS | JUDITH | BZO | 15.12.72 |
| BECKER | WILLI | MTD | 12.03.85 |
| BERGER | CHRISTA | BZO | 21.06.02 |
| BODENBACH | SVEN | MOR | 12.10.75 |
| CALIBATION | CAL | CAL | 01.10.02 |
| CIMIC | SENEM | THC | 12.07.72 |
| DÜRRER | TORSTEN | AMP | 01.12.72 |
| EBERT | NICOLE | CDC | 15.12.72 |
| FUHS | LILLI | BAR | 26.03.02 |
| GOLDBACH | TINA | MOR | 26.03.02 |
| HUPERT | KLAUS | CDC | 26.03.02 |
| INNERS | SIMONE | MTD | 26.03.02 |
| KARIN | KÜNST | LH | 26.03.02 |

Street: UNISTRASSE 4 State: BERLIN
City: BERLIN Country: DEUTSCHLAND
ZIP: 10789 ID: 15656-145640

Buttons: Delete, Add, Change, Cancel, Accept

Practice mode

Type in the patient's data

- Type in the patient's data (First Name, Name, Date Of Birth, Sex) into the form.
- click on **OK**
- Now you can perform an examination with this patient
- To edit the data of an existing patient click on **Load patient / change** and type in the new data

Address - Create New Patient

First Name: JOHN Name: SMITH
Date Of Birth: 19.02.1966 Sex: MALE

Patient ID: 451245 Group:

Street: MAIN STREET 14
City: UPTOWN ZIP: 78457
State:
Country:

Buttons: OK, Cancel

Laboratory mode

Type in the laboratory's data

- Type in the laboratory's data into the form
- click on **OK**
- Now you can perform an examination with these laboratory's data

New measurement - File / Sample ID insert

Working list: LAB-04-04-2003
Type of Test: AllergyScreen Panel 1 v3 D.TST
Lot#: K030325
Sample ID: 12345-6789
Date: 04.04.2003

Buttons: Cancel, OK

9 PERFORMING AN EXAMINATION

PREPARE MEASUREMENT

Patient's data

Make sure that the patient's data are acquired in the data-base.

Prepare measurement

After the end of the reaction time (also see: test conduction), please insert the test membrane into the holder of the RIDA® X-Screen.

Remark:

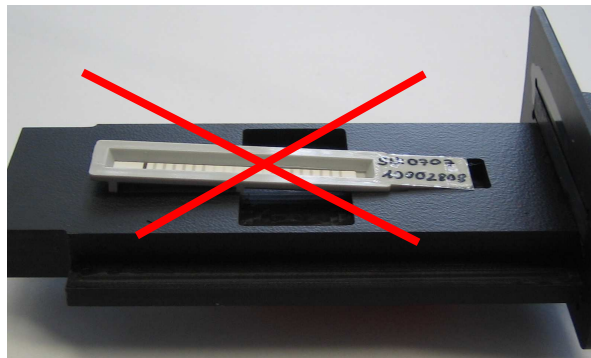
Please pay attention to a correct insert of the test membrane into the test membrane holder

Please put the test membrane into the depression the way it fits evenly, exactly and appropriately. Pay attention not to touch the surface of the membrane.

Correct



False



The test membrane holder has to be pushed in exactly into the RIDA® X-Screen. Please take care for a complete closing of the test membrane holder.

Correct



False



9 PERFORMING AN EXAMINATION

NEW EXAMINATION • OPENING/CHANGING PATIENT'S DATA

Choose patient

In the program:

MENU BAR



NEW EXAMINATION

- Choose a patient
- Click on **Accept** to continue

| Lastname | Firstname | Group | Date of birth |
|------------|-----------|-------|---------------|
| ABEL | BERND | ALL | 15.10.69 |
| ALFRED | BEN | METH | 11.12.71 |
| ANTON | RAINER | BAR | 15.07.64 |
| ATLAS | JUDITH | BZO | 15.12.72 |
| BECKER | WILLI | MTD | 12.03.85 |
| BERGER | CHRISTA | BZO | 21.06.02 |
| BODENBACH | SVEN | MOR | 12.10.75 |
| CALIBATION | CAL | CAL | 01.10.02 |
| CIMIC | SENEM | THC | 12.07.72 |
| DÜRRER | TORSTEN | AMP | 01.12.72 |
| EBERT | NICOLE | COC | 15.12.72 |
| FUHS | LILLI | BAR | 26.03.02 |
| GOLDBACH | TINA | MOR | 26.03.02 |
| HUPERT | KLAUS | COC | 26.03.02 |
| INNERS | SIMONE | MTD | 26.03.02 |
| KARIN | KÜNAST | LH | 26.03.02 |

Street UNISTRASSE 4 State BERLIN
City BERLIN Country DEUTSCHLAND
ZIP 10789 ID 15656-145640

Buttons: Delete, Add, Change, Cancel, Accept

Select test

In the program:

- Select a test
- Continue with **Accept**

| Test | Name |
|---------|---------------------------------|
| 7004004 | AllergyScreen Panel 1 v4 D |
| 7004004 | AllergyScreen Panel 1 v4 TR |
| 7004004 | AllergyScreen Panel 1 v4 UK |
| 7039004 | AllergyScreen Panel 1KO v4 UK |
| 7021004 | AllergyScreen Panel 1PE v4 E |
| 7005004 | AllergyScreen Panel 2 v4 D |
| 7005004 | AllergyScreen Panel 2 v4 TR |
| 7005004 | AllergyScreen Panel 2 v4 UK |
| 7036004 | AllergyScreen Panel 2H v4 UK |
| 7041004 | AllergyScreen Panel 2KO v4 UK |
| 7023004 | AllergyScreen Panel 2ME v4 E |
| 7025004 | AllergyScreen Panel 2MENA v4 UK |
| 7047004 | AllergyScreen Panel 2TR v4 TR |
| 7047004 | AllergyScreen Panel 2TR v4 UK |
| 7006004 | AllergyScreen Panel 3 v4 D |
| 7006004 | AllergyScreen Panel 3 v4 TR |
| 7006004 | AllergyScreen Panel 3 v4 UK |
| 7042004 | AllergyScreen Panel 3KO v4 UK |
| 7024004 | AllergyScreen Panel 3ME v4 E |
| 7026004 | AllergyScreen Panel 3MENA v4 UK |
| 7048004 | AllergyScreen Panel 3TR v4 TR |

Buttons: << Cancel, Accept >>

Camera contact

The RIDA® X-Screen software starts the camera.
This procedure takes a few seconds.

9 PERFORMING AN EXAMINATION

CAMERA PREVIEW • PICTURE ADOPTION

Camera preview

In the program:

Adopt the picture with

- **Continue**

or break off with

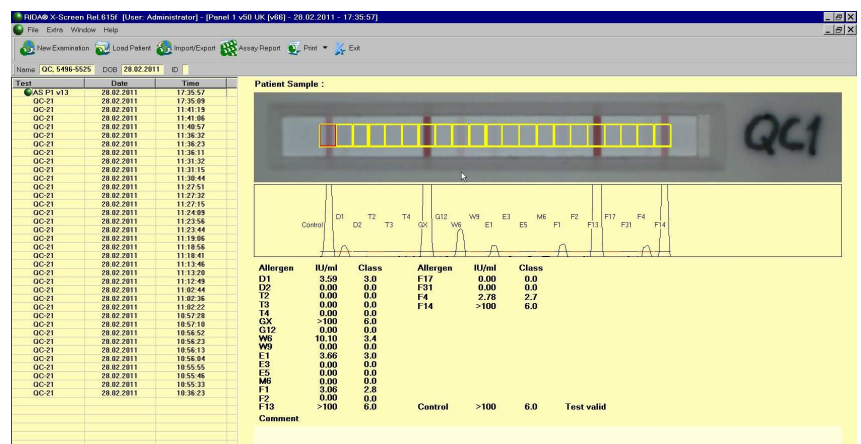
- **Cancel**



Picture adoption

The results appear on the screen after a few seconds

- analysed test strip/cassette
- densitometry evaluation
- calculated values



10 MEASUREMENT AND EVALUATION

MEASUREMENT DATA • CURRENT OR PRIOR MEASUREMENTS

Measurement data

Prior measurement

- Examinations, which were saved or archived, can be recalled by clicking the entry in the exam. list

▶ clicking on exam. list

RIDA® X-Screen Rel.615f [User: Administrator] - [Panel 1]

File Extra Window Help

New Examination Load Patient Import/Export

Name QC. 5496-5525 DOB 28.02.2011 ID

| Test | Date | Time |
|-----------|------------|----------|
| AS P1 v13 | 28.02.2011 | 17:35:57 |
| QC-21 | 28.02.2011 | 17:35:09 |
| QC-21 | 28.02.2011 | 11:41:19 |
| QC-21 | 28.02.2011 | 11:41:06 |
| QC-21 | 28.02.2011 | 11:40:57 |
| QC-21 | 28.02.2011 | 11:36:32 |
| QC-21 | 28.02.2011 | 11:36:23 |
| QC-21 | 28.02.2011 | 11:36:11 |
| QC-21 | 28.02.2011 | 11:31:32 |
| QC-21 | 28.02.2011 | 11:31:15 |

11 DELETING A PATIENT

DELETING PATIENT'S DATA

Deleting a patient

In the program:

MENU BAR

NEW EXAMINATION

- Select the patient, who is going to be deleted.
- Use **Delete**

Explorer ...

Name Firstname Date of birth

ALL AB CD EF GH IJ KL MN OP QR ST UVW XYZ

| Lastname | Firstname | Group | Date of birth |
|----------|-----------|-------|---------------|
| BAKER | NORMA | | 10.03.1954 |
| SMITH | JOHN | | 13.02.1953 |

Street State City Country ZIP ID

Delete Add Change Cancel Accept

Confirmation

- The selected patient's data will be deleted irrevocably
- Use **Yes**
- Now the patient's data are no longer available

RIDA X-Screen

Are the data of the patient to be irrevocably deleted?

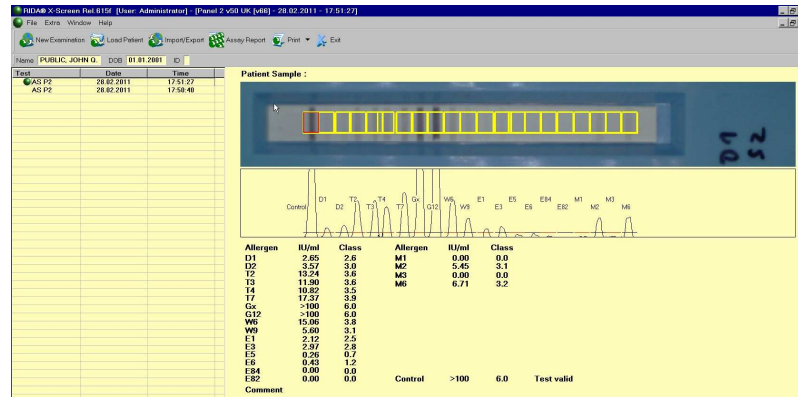
X No ✓ Yes

12 DELETING AN EXAMINATION

DELETING SINGLE MEASUREMENTS

Load patient

- Measurements, which were saved or archived, can be recalled by clicking the entry in the exam. list.



Deleting measurement data

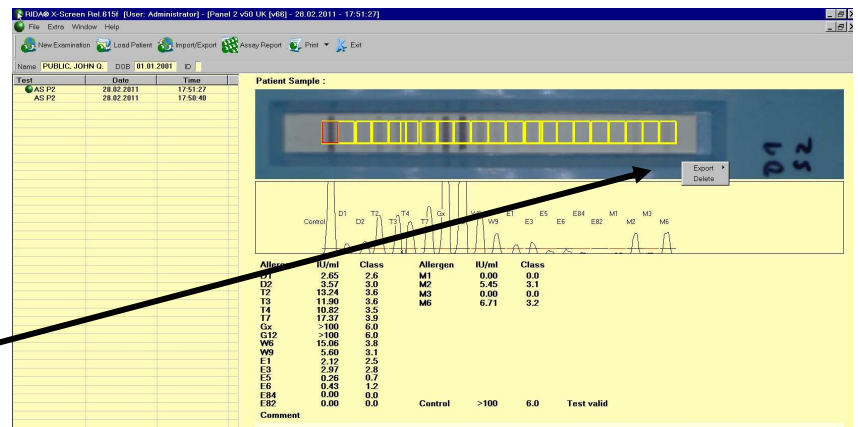
Load the measurement, which is going to be deleted

- Click on the result domain with the right mouse button
- The button

Export
Delete

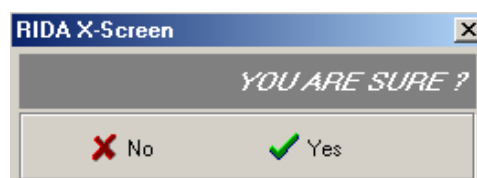
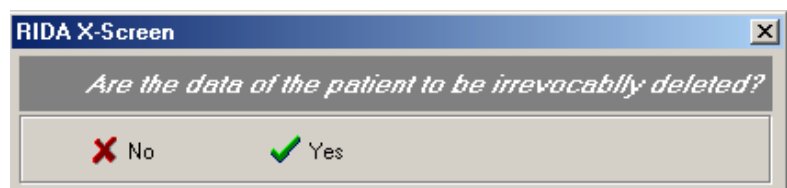
appears:

▶ Click on delete



Confirmation

- The measurement data chosen will be deleted irrevocably
- Use **Yes**
- Now the measurement data are no longer available



13 IMPORT/EXPORT OF EXAMINATIONS

DATA TRANSFER • SAVING DATA

Data transfer of single measurements

- You can import and export the examination data of any patient to and from any destination on the local drive or on your network.
- So you can exchange the results of the measurements between different **RIDA® X-Screen** Reader systems.

Data transfer

In the program:

MENU BAR



Select either ASCII or Reader

When having selected ASCII export is generated automatically. Confirm by clicking on **OK**.

The ASCII-file will be stored under C:\RAPID\Export

When having selected READER or PDF:

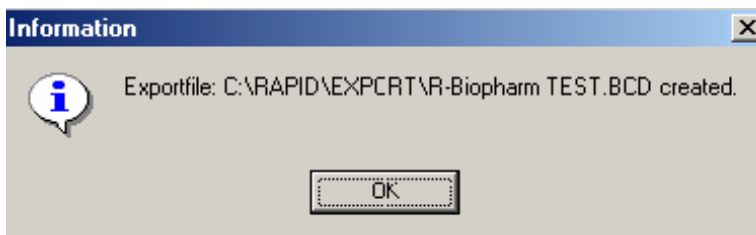
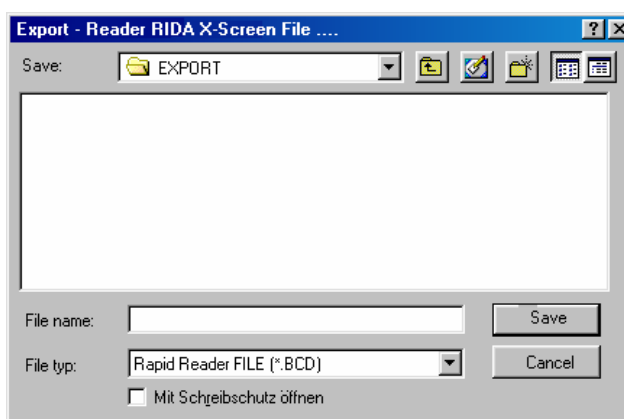
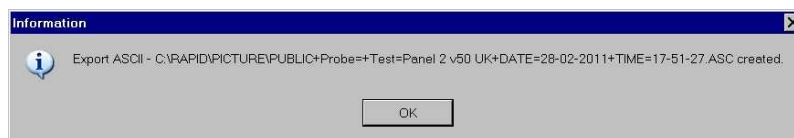
- Choose directory
- Enter file name
- Save file

The file is stored in the selected directory as a .BCD or .PDF file

Saving data

IMPORTANT !

- It is recommended to run back-ups of the acquired data on an external storage system on a regular basis
- The BCD-file might be sent to all RIDA® X-Screen users. Data can be shown at the receiver's places by clicking on import.



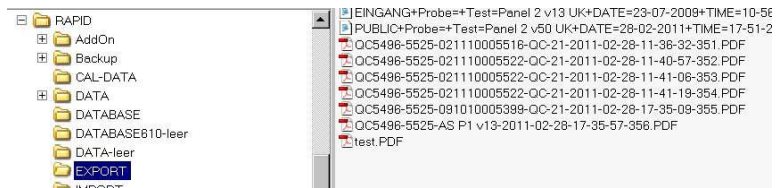
Export of several measurements

- You can printout or export as PDF or store in the clipboard the data of multiple measurements

Select all measurements you want to export and click in the list with the right mouse button, click on **Selected** and the on "PDF".

| | Date | Time |
|-----|------------|----------|
| 3 | 06.05.2009 | 16:20:15 |
| 3 | | 16:17:15 |
| v13 | | 00:57:54 |
| 3 | | 00:57:54 |
| v13 | 25.06.2008 | 00:57:54 |
| v13 | 25.06.2008 | 00:57:54 |
| v13 | 25.06.2008 | 00:57:54 |

Now all measurements will be stored under C:\Rapid\Export. The file name consists of the patient's name-the panel-date-time-running number.pdf



If you have selected "Clipboard" you can enter the measurement data in text editor programs or spread sheets.

14 PRINTOUT OF RESULTS

PREVIEW • PRINTOUT

Preview / printout

You can activate the **preview** and **printout** by using the icon **Print** in the respective window.

Preview and printout of the current result

In the program:

PRINT

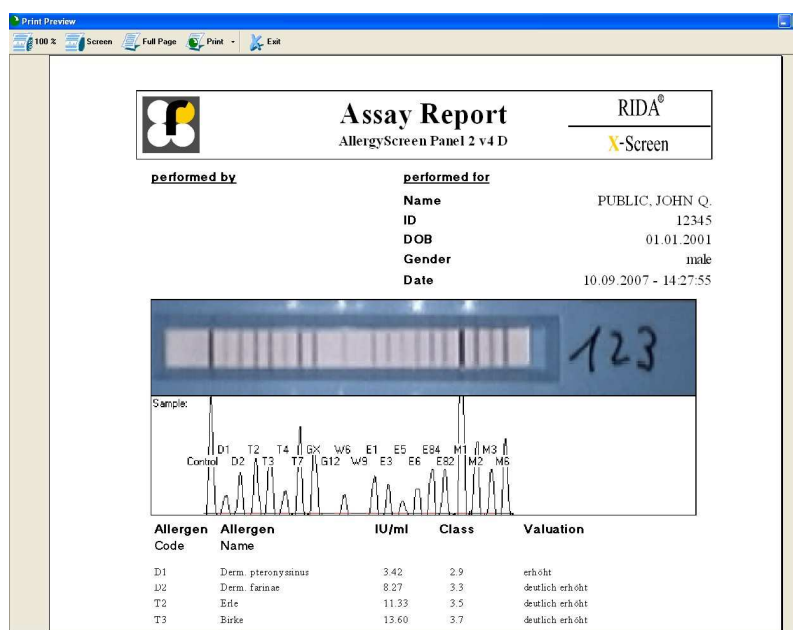
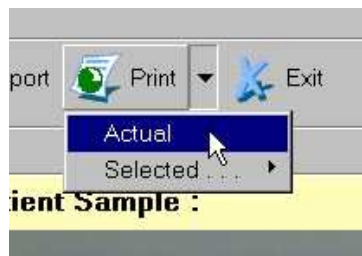


Actual

- The result is shown in the preview window

In order to print the preview click on the button **print** in this preview window.

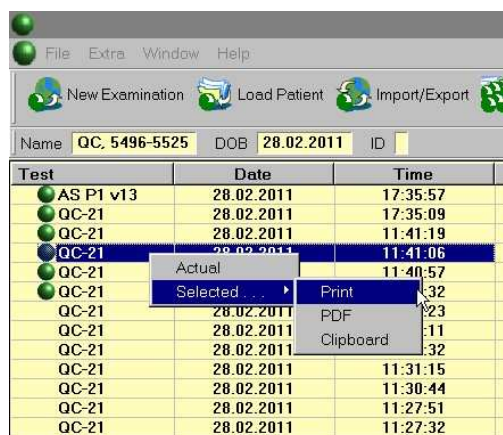
The report is printed out on the default printer of Windows.



Print out of several measurements

Select all measurements you want to printout and click in the list with the right mouse button, click on "Selected" and then on "Print".

Now all measurements will be printed as single reports.

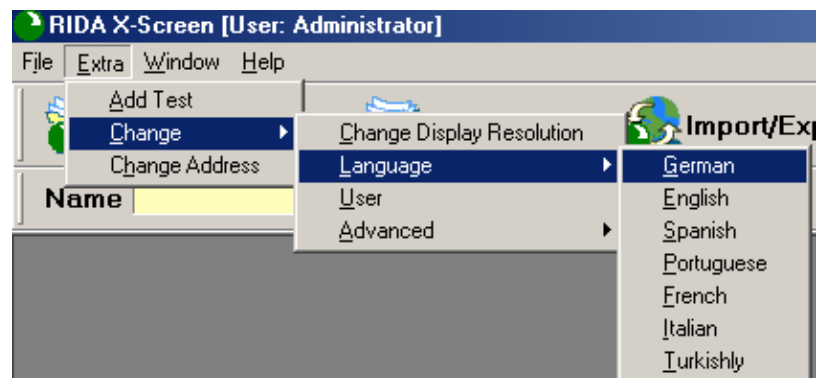


15 EXTRAS

SETTINGS • GRAPHIC MODUS • ADDRESS

Settings

The EXTRA option allows you to alter several settings.



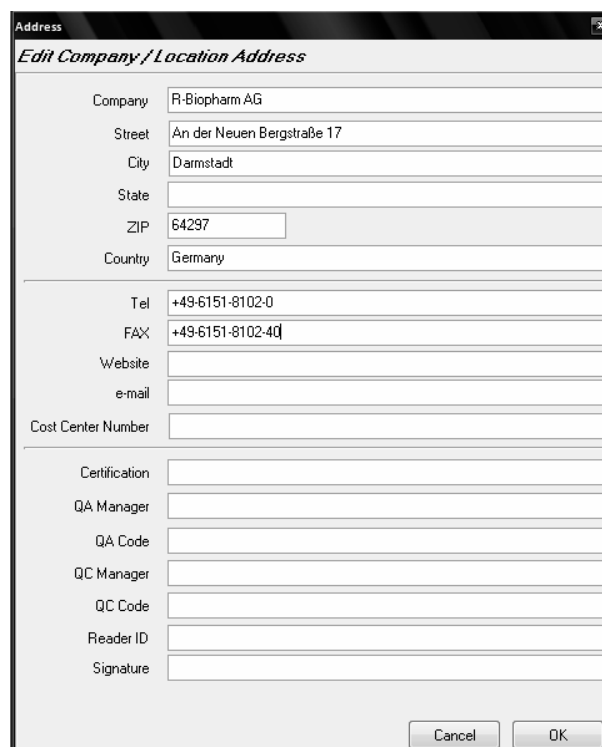
Address

You can edit the address of the location at which the examination is performed.

IN the program

MENU BAR

Extras ► Change address



16 CONTROL SAMPLE

QUALITY CONTROL

Control sample

The control sample is provided by the manufacturer for examination of the performance features of the **RIDA® X-Screen**.

By using the control sample troubles during the measurement of patient samples might be detected and/or quality control can be carried out.

The control sample is a membrane with 9 positive bands and 11 negative bands. The positive bands are evenly spread on the membrane surface to make sure that the camera is working properly over the complete membrane.

The results which the positive and the negative lines must achieve is stored in the rdf-file. If the control panel and the RIDA® X-Screen is working properly every line will be attributed with a green "passed"

If one or more lines achieve wrong values then either the panel is deteriorated or the camera is not working properly.

In order to find out the reason for the failed quality check of your system you should order another control panel. If the measurement is fine with the new one the old panel was deteriorated or in case the problem still exists then the camera must be checked from the manufacturer. Please contact your local distributor.

Caution

In case there has not been conducted a documented continuous examination by using the control sample, the manufacturer excludes every warranty for the measurement values.

Frequency of measurements by using the control sample should correspond to the location and safeguard a closed control of the system. These measurements should be entered into a separate table and a printout of the measurement values of the control sample should be archived.

See page 28 record of measurements of the control sample.

Performing control measurement

Control measurement is carried out by using the test **QC 21 v50 UK** which is already preinstalled.

If the test is not installed

please go to ► **MENU BAR** ► **EXTRAS** ► **ADD TEST**

and proceed according to chapter 7 "ADDING A NEW TEST". Carry out the measurement according to chapter 9 "PERFORMING AN EXAMINATION".

Printout of the operator and or QC-Manager

If the person who has performed the control panel and/or the person who is responsible for the quality control the data of these persons and the codes can be entered in the address in the lower part. See page 24 **Address**

Measuring range and interpretation

The measurement below is an example:

Line 1 (L1) ▶ passed / failed

Line 2 (L2) ▶ passed / failed

Line 3 (L3) ▶ passed / failed

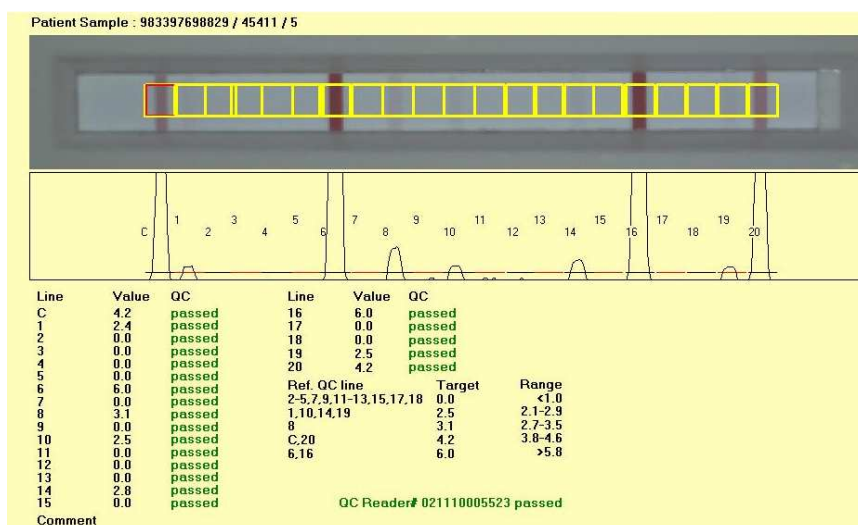
Line 4 (L4) ▶ passed / failed

•
•
•

When “failed” is stated in one or more lines the result is out of specification. Contact your technical support or distributor:

R-Biopharm AG • Telephone ++ 49 (0) 6151 8102-0

Control sample



Note:

- The control sample should be stored at room temperature under dark and dry conditions in the original package.
- Record the date opened on the package.
- However, after the first measurement the control sample should not be used longer than 6 months.
- You can obtain new control samples from your distributor:

R-Biopharm AG • Telephone ++ 49 (0) 6151 8102-0

Handling (control sample)

QUALITY CONTROL • RECORD

R-Biopharm AG

17 TROUBLE SHOOTING

MAINTENANCE

| Symptom / Message | Problem | Help |
|---|--|--|
| Target and source equal when importing | You tried to import a file that is already on the PC | <ul style="list-style-type: none"> The file is already on the PC |
| Image of test membrane / cassette seems off center or slope | The test membrane / cassette wasn't inserted accurately | <ul style="list-style-type: none"> Insert the test membrane / cassette properly into the holder Retry the examination |
| Image of test membrane / cassette seems very light or overexposed | The holder wasn't inserted entirely | <ul style="list-style-type: none"> Insert holder completely Retry the examination |
| Assessment is completely impossible | The wrong test membrane / cassette or the wrong test was selected | <ul style="list-style-type: none"> Insert correct test to the test list Select the correct test for examination Retry the examination |
| There is no visible light inside the RIDA® X-Screen device | Lack of power | <ul style="list-style-type: none"> Check the connection between the RIDA® X-Screen and the USB Port |
| Installation under Windows 2000 is not possible | Lacking administrator rights | <ul style="list-style-type: none"> You need to log in as administrator to be allowed to install |
| Enter System-Key number | RIDA® X-Screen has not been connected properly to the computer used | <ul style="list-style-type: none"> Exit the software Shut down computer Connect RIDA® X-Screen to the PC Start software |

| | | |
|-----------------------------------|--|--|
| Maintenance | Standard maintenance is not designated for the RIDA® X-Screen . In case of trouble or defective control samples, please contact: R-Biopharm AG • Telephone ++ 49 (0) 6151 8102-0 | |
| Cleaning of case | <ul style="list-style-type: none"> Wipe the case by using ordinary laboratory detergents (disinfectant). | <ul style="list-style-type: none"> Do not use acid agents or solvents . Please use scratch-free wipes. |
| Cleaning of test membrane holder: | <ul style="list-style-type: none"> Wipe and wipe out the test strip holder and depressions by using ordinary laboratory detergents (disinfectant). | <ul style="list-style-type: none"> Do not use acid agents or solvents . Please use scratch-free wipes. |

18 LICENCE CONDITIONS

License Agreement

Preface

The following conditions for your use of the RIDA[®] X-Screen READER SOFTWARE apply to end-users ("licensee").

By opening the sealed data carrier package you agree to the following licence agreement. Please, read this agreement carefully.

If you do not agree to the conditions mentioned below you are not allowed to open the sealed data carrier package. In this case **do not open the package** and return it immediately as well as all other parts of the purchased product (including all written documents or material, hardware components and packing) to the place you bought it from.

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- 10) Warranty and liability
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Should a defect arise as per this sentence 10 which cannot be solved by replacing components within a reasonable period of time the buyer is entitled to ask for a reduction in price or cancellation of the contract.
R-BIOPHARM AG does not grant entirely faultless software due to the reasons mentioned in sentence 1 of this contract. R-BIOPHARM AG does not warrant that the software entirely meets the purpose and request of the buyer himself or works without problems when it is combined with other software programmes chosen by the buyer.
The buyer himself is responsible for the correct choice and combination of products, the results of the use of software as well as the results he intends to achieve or gets. The same applies to the written material accompanying the software.
In case the basic software is not usable due to reasons mentioned in sentence 1 the buyer may cancel the contract. The same applies to R-BIOPHARM AG if production of a usable software as per sentence 1 is not possible within an adequate expenditure range.
R-BIOPHARM AG is not responsible for damages unless a damage is the result of intention or negligence by R-BIOPHARM AG. Liability for gross negligence is excluded towards businessmen. The liability regarding assured characteristics remains untouched. Liability for non-insured subsequent damages is also excluded.
- 11) Place of Jurisdiction
German law only applies to this contract. The place of jurisdiction is Darmstadt/Germany.
Concerning questions regarding these licence conditions, please contact: R-BIOPHARM AG AG, An der Neuen Bergstr. 17, 64297 Darmstadt, Germany.